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Monday, March 25, 2002

Examiner Joseph Woitach
Group 1632

DRAFT!! INFORMAL!!
DO NOT ENTER!!!

VIA FACSIMILE ONLY 013-1-703-746-5192

Dear Examiner Woitach,

In re application of: Sara Lavi
Serial No. 09/029,479 Group Art Unit: 1632
Filed: 10/21/98 Examiner: Woitach, J.

For: MANIPULATION AND DETECTION OF PROTEIN PHOSPHATASE 2C - PP2Cα - EXPRESSION IN TUMOR CELLS FOR CANCER THERAPY, PREVENTION AND DETECTION

Below please find some comments regarding the above-referenced Application. Briefly, the present claims have been stated to be free of the prior art, but a number of objections have been raised based on lack of support in the specification. These objections include the lack of support for particular teachings of cancer; the lack of provision of sufficient information to enable one of ordinary skill in the art to select vectors, etc for gene therapy; and the general unpredictability of gene therapy.

With regard to the lack of support regarding the types of cancer for which the present invention would be useful, and the ability to use the teachings of the present invention in order to select those types of cancer, Applicant feels that in fact sufficient information has been provided. As described in greater detail below, examples of various cancers are given, with teachings directed to the use of the method of the present invention in their treatment. These different types of cancers have at least one characteristic in common: an alteration (specifically, a decrease) in PP2Cα gene activity. Therefore Applicant has amended claim 65 to indicate that the detection of a type of cancer having this characteristic is the first step of the method. Applicant

feels that the specification includes sufficient support for this concept, as there are extensive teachings on the detection of a decrease in PP2Cα gene activity in a tissue.

Second, with regard to the selection of vectors, in fact various teachings are given in the present Application for enabling one of ordinary skill in the art to select a suitable vector. Alleged lack of predictability for any one vector does not negate the teachings of several different vectors, such that one of ordinary skill in the art could be reasonably expected to obtain a suitable mechanism for introducing the PP2Cα gene by following the teachings of the present Application *in their entirety*, without isolating one particular component. As noted in greater detail below, not only are a number of suitable vectors described for operation with the present invention, but in fact PP2Cα has been shown to be operative as a drug. The present inventor and her coworkers reported the use of conjugates of PP2Cα as a specific intracellular antitumor drug.

Third, with regard to the general unpredictability of gene therapy, please note that at the time of invention, and filing of the present Application, various gene therapy protocols were known in the art to be operative. Unless hindsight is (erroneously) applied as a standard, then at the time of filing, the information provided concerning gene therapy protocols certainly would have been considered to be sufficient by one of ordinary skill in the art.

Please consider the specific amendments and remarks given below:

In response to the Office Action of October 1, 2001, please amend the application as follows:

IN THE CLAIMS

Please amend claim 65 as follows:

65. (Twice Amended) A method of treating cancer in a patient comprising the steps of:

(a) detecting a type of cancerous cells in the patient wherein a decrease in PP2Cα gene activity is detected;

(b) preparing a vector specific to said type of cancerous cells comprising an expression control sequence operatively linked to the nucleic acid sequence of a mammalian PP2Cα gene, said vector being capable of targeting said cancerous cells, and

(c) administering to the patient a therapeutically effective amount of a composition comprising said vector as an active ingredient, thereby treating the cancer in the patient.